

scheduled inspections, inspections initiated to investigate recalls or other similar actions, and inspections initiated specifically to review your postmarket surveillance plan. We may also inspect any other person or site involved in your postmarket surveillance, such as investigators or contractors. Any person authorized to grant access to a facility must permit authorized FDA employees to enter and inspect any facility where the device is held or where records regarding postmarket surveillance are held.

§ 822.36 Can you inspect and copy the records related to my postmarket surveillance plan?

We may, at a reasonable time and in a reasonable manner, inspect and copy any records pertaining to the conduct of postmarket surveillance that are required to be kept by this regulation. You must be able to produce records and information required by this regulation that are in the possession of others under contract with you to conduct the postmarket surveillance. Those who have signed agreements or are under contract with you must also produce the records and information upon our request. This information must be produced within 72 hours of the initiation of the inspection. We generally will redact information pertaining to individual subjects prior to copying those records, unless there are extenuating circumstances.

§ 822.37 Under what circumstances would you inspect records identifying subjects?

We can inspect and copy records identifying subjects under the same circumstances that we can inspect any records relating to postmarket surveillance. We are likely to be interested in such records if we have reason to believe that required reports have not been submitted, or are incomplete, inaccurate, false, or misleading.

§ 822.38 What reports must I submit to you?

You must submit interim and final reports as specified in your approved postmarket surveillance plan. In addition, we may ask you to submit additional information when we believe

that the information is necessary for the protection of the public health and implementation of the act. We will also state the reason or purpose for the request and how we will use the information.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

Sec.

860.1 Scope.

860.3 Definitions.

860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

860.7 Determination of safety and effectiveness.

Subpart B—Classification

860.84 Classification procedures for “old devices.”

860.93 Classification of implants, life-supporting or life-sustaining devices.

860.95 Exemptions from sections 510, 519, and 520(f) of the act.

Subpart C—Reclassification

860.120 General.

860.123 Reclassification petition: Content and form.

860.125 Consultation with panels.

860.130 General procedures under section 513(e) of the act.

860.132 Procedures when the Commissioner initiates a performance standard or pre-market approval proceeding under section 514(b) or 515(b) of the act.

860.134 Procedures for “new devices” under section 513(f) of the act and reclassification of certain devices.

860.136 Procedures for transitional products under section 520(l) of the act.

AUTHORITY: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

SOURCE: 43 FR 32993, July 28, 1978, unless otherwise noted.

Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.